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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,032	10/03/2003	Jan Nilsson	7303CIP	1020

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Matthew E. Connors
Gauthier & Connors LLP
225 Franklin Street, Suite 3300
Boston, MA 02110

EXAMINER

CROWDER, CHUN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,032

Applicant(s)

NILSSON ET AL.

Examiner

Chun Crowder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/27/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Restriction Requirement

1. Applicant's Amendment, filed 05/27/2004, is acknowledged.
Claims 2, 5-28, 33-50 have been amended.
Claims 1-51 are pending.
2. It is noted that claims 1-21 are directed to the "use" of recombinant human antibody or antibody fragment directed towards at least one oxidized fragment of apolipoprotein B. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).
3. Therefore, claims 1-21 have been withdrawn from consideration as being drawn to non-statutory subject matter. If these claims are amended to recite statutory subject matter, the amended claims may be rejoined with the appropriate invention as set forth below.
4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 22, 23, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:1 and the variable light region of SEQ ID NO:2, classified in Class 530, subclass 387.1, and Class 424, subclass 130.1.

- II. Claims 22, 24, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:3 and the variable light region of SEQ ID NO:4, Class 530, subclass 387.1, and Class 424, subclass 130.1.
- III. Claims 22, 25, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:5 and the variable light region of SEQ ID NO:6, Class 530, subclass 387.1, and Class 424, subclass 130.1.
- IV. Claims 22, 26, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:7 and the variable light region of SEQ ID NO:8, Class 530, subclass 387.1, and Class 424, subclass 130.1.
- V. Claims 22, 27, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:9 and the variable light region of SEQ ID NO:10, Class 530, subclass 387.1, and Class 424, subclass 130.1.
- VI. Claims 22, 28, and 51, drawn to an antibody and a pharmaceutical composition raised against fragments of apo B100 comprising a variable heavy region of SEQ ID NO:11 and the variable light region of SEQ ID NO:12, Class 530, subclass 387.1, and Class 424, subclass 130.1.

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VII-XII. Claim 29, drawn to a method for preparation of an isolated antibody using a fragment library to for making specific antibody fragments against oxideized peptides derived from Apo B100, classified in Class 435, subclasses 7.1, and 69.1.

Applicant is required to elect one antibody with specific sequences for variable heavy region and the variable light region.

XIII-XVIII. Claims 30-31, drawn to a method for amplification of an isolated human antibody using recombinant technology, classified in Class 435, subclasses 6 and 69.1.

Applicant is required to elect one antibody with specific sequences for variable heavy region and the variable light region.

XIX. Claims 32-35, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:1 and the variable light region of SEQ ID NO:2, classified in Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

XX. Claims 32-34, and 36, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:3 and the variable light region of SEQ ID NO:4, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

- XXI. Claims 32-34, and 37, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:5 and the variable light region of SEQ ID NO:6, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

- XXII. Claims 32-34, and 38, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:7 and the variable light region of SEQ ID NO:8, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

- XXIII. Claims 32-34, and 39, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:9 and the variable light region of SEQ ID NO:10, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

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XXIV. Claims 32-34, and 40, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:11 and the variable light region of SEQ ID NO:12, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

XXV. Claims 32-34, and 41, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:19 and the variable light region of SEQ ID NO:20, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

XXVI. Claims 32-34, and 42, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:21 and the variable light region of SEQ ID NO:22, classified in Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

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XXVII. Claims 32-34, and 43, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:23 and the variable light region of SEQ ID NO:24, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

XXVIII. Claims 32-34, and 44, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:25 and the variable light region of SEQ ID NO:26, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

XXIX. Claims 32-34, and 45, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:27 and the variable light region of SEQ ID NO:28, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

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XXX. Claims 32-34, and 46, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:29 and the variable light region of SEQ ID NO:30, classified in Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

XXXI. Claims 32-34, and 47, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:31 and the variable light region of SEQ ID NO:32, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

XXXII. Claims 32-34, and 48, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:33 and the variable light region of SEQ ID NO:34, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a **specific** oxidized fragment for generating the antibody.

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XXXIII. Claims 32-34, and 49, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:35 and the variable light region of SEQ ID NO:36, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

XXXIV. Claims 32-34, and 50, drawn to a method for passive immunization of mammals wherein an isolated human antibody comprises the variable heavy region of SEQ ID NO:37 and the variable light region of SEQ ID NO:38, Class 424, subclasses 130.1 and 139.1.

Applicant is required to elect a specific oxidized fragment for generating the antibody.

5. Groups I-VI are different products. The products are patentably distinct because their structures, physicochemical properties and/mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Further, search for one antibody will not anticipate nor will it render the other antibody obvious; thus they require non-coextensive searches in the scientific literature. There for each product is patentably distinct, and searching of these inventions would impose an undue burden.

6. Groups I-VI and VII-XXXIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case, the product can be made using an amino acid synthesizer or by various biochemical or recombinant techniques.

Groups VII-XXXIV are different methods. The methods differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such it would be burdensome to search these Inventions together.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

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claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.

Patent Examiner

September 19, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
9/20/05